element **34** while an elution fluid is forced to flow through the chamber, releasing the analyte from the filter **60** into the elution fluid.

[0200] The top and base substrates **54** and **58** are preferably low cost molded plastic parts, and the middle substrate **56** is preferably a plastic flex circuit. The device **31** may be fabricated by precutting the filter **60** to size and then assembling the filter **60** and the substrates **54**, **56**, and **58** using adhesives, such as glue, or by welding, e.g. ultrasonic welding.

[0201] FIG. **16** shows another exemplary cartridge of the invention. The cartridge **161** is comprised of a top portion **163** and bottom portion **165** with a middle portion **167** therebetween. The middle portion **167** is preferably a printed circuit board (or flex circuit) having electrical circuitry **169**. Mating of board **167** with bottom **165** forms one wall of the fluid flow regions. The sample flow path includes, in a downstream direction, a lysing chamber **173**, a flow-through chip **177**, and a vented waste chamber **203**. The elution flow path includes the flow through chip **177**, a reagent chamber **179**, and a reaction chamber **181**.

[0202] As shown in FIG. **16** and the detail of FIG. **17**, the lysing chamber **173** has a chemically treated filter paper **183** which accepts the sample. A cap **185** is connected to the top by a flexible arm **187** and made to cover the lysing chamber **173** after the sample is added. The cap includes a membrane **189** made of material such as Goretex® which allows the transmission of gases but prevents the flow of liquid. A desiccant **191** is located in the cap on top of the membrane **189**. A heater **193** is located on flex circuit **167** below the sample port and heats the filter paper **183** and the sample when the cap is in a closed position.

[0203] In operation, after the sample is added to the filter paper **183**, the heater dries the sample and moisture rises through the membrane **189** and is absorbed into the desiccant **191**. At the same time, chemicals impregnated in the paper lyse the cells and bind various biological molecules to the paper itself. The cartridge bottom includes a wash storage chamber **195** which is connected by channel **197** to the sample port in an area beneath the filter paper **183**. Thus, after the sample is dried, wash fluid is forced to flow from C to D, as depicted in FIG. **17**, through the filter paper **183** to wash out and/or elute processing chemicals which are present in the filter paper. The waste processing chemicals and wash are prevented from flowing into the desiccant by membrane **189** and exit the sample port through outlet D.

[0204] As shown in FIG. **16** and the detail of FIG. **18**, waste fluid is washed away from the sample flow path and redirected into waste chamber **201** by a flow diverter **174**. The flow diverters **174**, **175** may comprise a capillary or hydrophobic membrane to allow fluid to pass when a threshold back pressure develops in the regions before the diverters. The waste fluid filling waste chamber **201** creates pressure in region **176**. Once the waste chamber **201** is filled with fluid, the pressure in region **176** triggers the diverter **174** to allow fluid to pass. Simultaneously, the sample in lysing chamber **173** is heated by heater **193** causing the nucleic acid to be released from the filter paper **183** and flow out through outlet D.

[0205] The sample flows along the sample flow path through diverter **174** and into chip **177** where target analyte is extracted. Waste components flowing from the chip **177** are redirected by flow diverter **175** to flow into a second waste chamber **203**. Waste components collecting in the second waste chamber **203** create back pressure in region **178**. Once waste components fill the second waste chamber **203**, the pressure in region **178** is sufficient to release diverter **175** and allow fluid to pass. Simultaneously, a voltage or heat is applied to the chip **177** through connectors in the flex circuit **167**, releasing the target analyte. Thereby, the analyte flows down the elution flow path and into a reagent chamber **179** where predried reagents are reconstituted and mixed with the analyte. The mixture continues to flow into and fill the reaction chamber **181**. The elution flow path ends at reaction chamber **181** where amplification, e.g. PCR, takes place.

[0206] Historically, the lysis step in sample processing has been a time consuming and difficult task, especially for spores and certain cell structures. In further embodiments, the present invention addresses this problem by providing a method and device for the rapid lysing of sample components, e.g., cells, spores, or microorganisms, using ultrasound. The ultrasonic lysing may be performed in a fully integrated cartridge, such as the cartridge of FIG. **2**, or may be performed with a cartridge that performs only lysing of sample components.

[0207] FIG. **19** shows an exemplary device for lysing sample components, e.g., cells, spores, or microorganisms. The device includes a cartridge **70** having an inlet port **72** for introducing the sample into the cartridge, and a lysing chamber **74** in fluid communication with the inlet port **72** for receiving the sample. The cartridge also includes an outlet port **76** for exit of the sample from the chamber **74**.

[0208] The chamber **74** contains a solid phase for capturing the components of the sample to be lysed. Suitable solid phases for capturing cells, spores, or microorganisms include, e.g., filters, beads, fibers, membranes, glass wool, filter paper, polymers and gels. The solid phase may capture the desired sample components through physical retention, e.g., size exclusion, through affinity retention, or through chemical selection. In the presently preferred embodiment, the solid phase comprises a membrane or filter **86** for capturing the components to be lysed. Suitable filter materials include glass, fiberglass, nylon, nylon derivatives, cellulose, cellulose derivatives, and other polymers. In an alternative embodiment, the solid phase comprises polystyrene, silica, agarose, cellulose, or acrylamide beads.

[0209] The device also includes an ultrasonic transducer, such as an ultrasonic horn **88**, that is coupled to the cartridge for transferring ultrasonic energy to the components captured on the solid phase, e.g., captured on filter **86**. A miniature ultrasonic horn is presently preferred as the transducer because it allows focusing of ultrasonic energy onto the components captured on the solid phase. To this end, it is also preferred that the horn **88** be coupled to the cartridge **70** such that the longitudinal axis of the horn **88** is perpendicular to the filter **86**. Additionally, the horn **88** is preferably coupled directly to a wall of the chamber **74**.

[0210] In operation, a sample fluid is introduced into the inlet port **72** and forced to flow into chamber **74**. As the sample flows into the chamber **74**, the sample components to be lysed are captured by the filter **86**. The sample may be made to flow continually through the chamber **74**, or the cartridge **70** may include flow controllers, e.g. valves, for holding the sample fluid in chamber **74** for lysis. Continuous flow processing is suitable for larger sample volumes, e.g. 1 mL or greater, while holding the sample in the chamber **74** may be appropriate for smaller sample volumes, e.g. 100 μl.

[0211] The sample components captured on the filter **86** are then lysed by transferring ultrasonic energy from the horn **88** to the captured components. The ultrasonic energy causes